

## **REMARKS**

Claims 1-19, 23, 25 and 28 are pending. Claim 26 has been cancelled without prejudice. Applicant reserves the right to prosecute the subject matter of the cancelled claim in one or more related applications. Claims 10, 25, and 28 been amended. Specifically, claim 10 has been amended to correct a typographic error. Claim 25 has been amended to recite that the patch unit comprises an impermeable layer on the surface of the backing layer and a drug-in-matrix layer comprising buprenorphine disposed on the impermeable layer. Claim 28 has been amended to correct the dependency of the claim. Support for the claim amendments can be found in the originally-filed specification at, *e.g.*, page 7, lines 22-24. No new matter has been added.

Entry of the above claim amendments and reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

### **I. CLAIM REJECTION UNDER 35 U.S.C. § 103(a)**

#### **A. Claims 25 and 28 Are Patentable Over Pagedas In View of Cleary**

The Examiner has rejected claims 25, 26 and 28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,221,384 to Pagedas (“Pagedas”) in view of U.S. Patent No. 5,006,342 to Cleary *et al.* (“Cleary”). Specifically, in response to Applicant’s remarks submitted on April 17, 2009, the Examiner contends that Figures 1-2 and 4-6 in Pagedas “clearly show a border surrounding the membrane comprising the drug” and “one of ordinary skill would determine this border to comprise an adhesive strip without a drug admixed” (Office Action, page 7). For the following reasons, Applicant respectfully disagrees.

As a preliminary matter, claim 26 has been cancelled and the rejection of this claim therefore is moot. In order to expedite prosecution, claim 25 has been amended to recite a method of delivering a drug using a transdermal delivery system comprising a plurality of patch units, each of which comprises a backing layer with one or more drug-free borders, an impermeable layer disposed on the backing layer, a drug-in-matrix layer comprising buprenorphine disposed on the impermeable layer, and an adhesive layer. A portion of the adhesive layer is disposed on the drug-free borders of the backing layer. Since the Examiner has withdrawn her rejection of claim 1 in view of the addition of the claim limitation regarding the

impermeable layer on the surface of the backing layer, claim 25 is also believed to patentable over Pagedas an Clearly.

Furthermore, Applicant respectfully disagrees with the Examiner's statement that Figures 1-2 and 4-6 of Pagedas show "a border surrounding the membrane comprising the drug", *i.e.*, a drug-free border. The border shown in, for example, Figs. 1 and 2 of Pagedas, is a portion of the backing layer of the segmented dosage unit (which corresponds to the release liner in the present claimed method), not a portion of the impermeable coating of the segmented dosage unit (which corresponds to the backing layer in the presented claimed method). This is further illustrated in Fig. 4, which shows a segmented dosage unit being removed from the backing layer (*i.e.*, the release liner), and its related text, which states that surface 30a of the segmented dosage unit is then adhered to the skin of the patient (col. 3, lines 23-25; col. 3, line 67 to col. 4, line 2). Thus, the figures that the Examiner relies upon at best show a drug-free border of the release liner, but not a drug-free border of the backing layer, as recited in the present claims.

Moreover, the statement that the adhesive in Pagedas may be over the entire surface or may define an adhesive free surface (*see* col. 3, lines 20-35; Office Action, page 7) merely suggests that a portion of the membrane layer may be adhesive-free. It by no means, however, teaches or suggests that the adhesive covers the drug-free border of the impermeable coating (which Applicant submits is non-existent in Pagedas). In fact, neither of Figs. 3 and 3a, where a cross-sectional view of different embodiments of the segmented dosage unit is shown, shows an adhesive on the drug-free border of the impermeable coating. To the contrary, these figures illustrate that the membrane and the impermeable coating always overlap coextensively. In addition, Pagedas discloses "severable perforations transversely extending through each of said layers" (col. 4, lines 29-30 and 46-47; *see also* col. 6, lines 5-6) (emphasis added). The layers that Pagedas refers to include an impermeable coating layer, an adhesive layer and a layer containing a measured amount of a pharmaceutical (col. 4, lines 22-26 and 41-44). Thus, since these severing means that separate Pagedas' segmented dosage units extend through each of these layers, there cannot be a border of the impermeable layer that is drug-free and covered by an adhesive.

The Examiner acknowledges that the transdermal patch in Clearly has a substantially different structure from that in Pagedas. Therefore, Clearly does not cure any deficiency that Pagedas suffers as discussed above.

For the foregoing reasons, claim 25 and 28 are believed to be patentable over Pagedas in view of Cleary. Withdrawal of this rejection and allowance of claim 25 and 28 are respectfully requested.

**B. Claim 1-19 and 23 Are Patentable Over Kwiatek In View Of Pagedas**

Claims 1-9 and 23 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,573,996 to Kwiatek *et al.* (“Kwiatek”) in view of Pagedas. Specifically, the Examiner contends that Kwiatek teaches an impermeable adhesive surface which is adhered to the backing member and overlaps completely the backing member (Office Action, page 9), and Pagedas teaches a plurality of segmented dosage units (*id.* at 11). Therefore, the Examiner contends that it would have been obvious to one of ordinary skill in the art to combine the teachings of Kwiatek and Pagedas to arrive at the presently claimed methods (*id.*, at 12). For the following reasons, Applicant respectfully disagrees.

Kwiatek does not teach or suggest a drug-in-matrix type transdermal patch as recited in the present claims. In fact, Kwiatek only contemplates two types of drug layers, *i.e.*, the drug-in-reservoir type and the drug-in-adhesive type (*see* col. 1, lines 21-35; Figures 1-8). Pagedas, on the other hand, teaches that the pharmaceutical dosage layer may be in form of a separate encapsulated layer or may be microdispersed on the surface of the permeable membrane (col. 3, lines 49-52; Figs. 3 and 3a). Therefore, Applicant submits that one of ordinary skill in the art would not find any teaching, suggestion, motivation, or reasonable expectation of success to combine or modify the teachings of Kwiatek and Pagedas to arrive at the presently claimed methods.

Moreover, even assuming that the teachings of Kwiatek and Pagedas can be combined, their combination still would not result in the claimed method. For example, neither reference teaches or suggests a patch unit comprising an impermeable layer disposed on the backing layer, and an adhesive a portion of which covers the drug-free order of the backing layer as recited in claim 1.

Accordingly, the pending claims are believed to be patentable over Kwiatek and Pagedas and Applicant respectfully requests that the rejection be withdrawn.

## II. CLAIM OBJECTION

The Examiner objected to claim 10 because the term "octanol" has been misspelled. The typographical error in claim 10 has been corrected. Accordingly, the objection should be withdrawn.

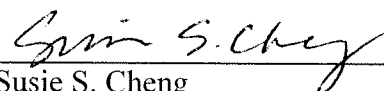
## CONCLUSION

Thus, as the claim rejections and objection are believed to be overcome, the pending claims are believed to be in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

No other fees are believed to be due for this submission. If any fees are due, please charge the required fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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